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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/802,152   | 03/08/2001  | Hideji Tajima        | 10287.41            | 6205             |
| 27683  | 7590        | 07/23/2004           | EXAMINER            |                  |
| HAYNES AND BOONE, LLP<br>901 MAIN STREET, SUITE 3100<br>DALLAS, TX 75202 |             |                      | FORMAN, BETTY J     |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 1634                 |                     |                  |

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                       |                  |
|------------------------------|-----------------------|------------------|
| <b>Office Action Summary</b> | Application No.       | Applicant(s)     |
|                              | 09/802,152            | TAJIMA, HIDEJI   |
|                              | Examiner<br>BJ Forman | Art Unit<br>1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 04 May 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 2-7,24,25,27-29 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 2-7 24-25 27-29 36-38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**FINAL ACTION**

***Status of the Claims***

1. This action is in response to papers filed 4 May 2004 in which claims 2-7, 24-25, 27-29 and 36-37 were amended and claims 1, 8-22, 30-35 and 39-49 were canceled. All of the amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 5 November 2003, not reiterated below, are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection, necessitated by amendment, are discussed.

Claims 2-7, 24-25, 27-29 and 36-38 are under prosecution.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 24-25, 27-29 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Stimpson (U.S. Patent No. 6,037,186, filed 16 July 1997).

Regarding Claim 24, Stimpson discloses a method of manufacturing an integrated support comprising a positioning step for positioning and fixing substances for detection at predetermined locations on at least one base member at intervals (Fig. 2) and an integration step for rolling said base member to give integration so that a surface in which the substances for detection are fixed and the location of the substances for detection is selected from the surface of the base member and in the base member when the base member is made from a porous material (Column 9, lines 18-39; Column 10, lines 16-57; and Column 12, line 56-Column 13, line 59) wherein said base member has a rod shape or a long and slender shape (Column 3, lines 36-46) and wherein said positioning a suspension of substance for detection is positioned by being dispensed, imprinted or impregnated onto said base member at a position which corresponds to the chemical structure (Column 7, lines 19-28 and Column 9, lines 18-42).

Regarding Claim 25, Stimpson discloses the method wherein said base member is arranged in such a way that the base member either prevents or enables expansion while bringing side portions into contact with each other or maintaining spacing or sandwiching (Column 5, line 47-Column 6, line 7 and Fig. 1A and 2C).

Regarding Claim 27, Stimpson discloses the method wherein said positioning a suspension of substance for detection is positioned by being dispensed, imprinted or impregnated onto said base member (Column 7, lines 19-28 and Column 9, lines 18-42) wherein said base member is made from a porous material, a fibrous material or an impregnating material (Column 9, lines 18-39 and Column 10, lines 16-57).

Regarding Claim 28, Stimpson discloses the method wherein in the integrating step, said base member and/or an auxiliary member in such a way that the auxiliary is either releasable or non-releasable (i.e. when the support is rod shaped the rods are arranged in a

sheath which secures the rod arrangement, Column 13, lines 42-43 and when the support is a long and slender shape the base member is rolled the integrity of the rolled base member is maintained Column 6, lines 2-6 and where either base member is secured with an adhesive which provides a solid integrated support i.e. non-releasable Column 5, lines 56-61).

Regarding Claim 29, Stimpson discloses the method wherein in the positioning step said substances are fixed and supported onto said base member by drying i.e. placed on paper towel (Example 6, Column 16, lines 18-23).

Regarding Claim 36, Stimpson discloses a method of manufacturing an integrated support comprising a positioning step for positioning and fixing substances for detection at predetermined locations on at least one base member at intervals (Fig. 2) and an integration step for rolling said base member to give integration so that a surface in which the substances for detection are fixed and the location of the substances for detection is selected from the surface of the base member and in the base member when the base member is made from a porous material (Column 9, lines 18-39; Column 10, lines 16-57; and Column 12, line 56-Column 13, line 59) wherein passing a heating fluid (sample) through the integrated support, the integrated support is heated (Example 5, Column 15, line 37-Column 16, line 13).

#### **Response to Arguments**

4. Applicant argues that Stimpson fails to disclose the claimed positioning a suspension of substance for detection is positioned by being dispensed, imprinted or impregnated onto said base member at a position which corresponds to the chemical structure. The argument has been considered but is not found persuasive. Stimpson clearly teaches positing comprising dispensing a substance comprising a predetermined chemical structure e.g. DNA (Column 7, lines 19-28) wherein the DNA is dispensed onto the base member at a location corresponding to the DNA e.g. reagent lines (Column 7, line 28-30), array elements (Column 7, lines 49-54) or binding zone (Column 9, lines 18-42). The claims are broadly drawn to a location which

“corresponds” to the chemical structure. The broadly claimed location is encompassed by the locations of Stimpson i.e. reagent lines, array elements and/or binding zone) of Stimpson because Stimpson specifically dispenses the DNA onto the locations (Column 7, lines 19-60).

Applicant argues that Stimpson does not teach “by passing a heating fluid or a cooling fluid through an integrated support, an integrated minute vessel, or a permeable membrane, the integrated support, integrated minute vessel, or permeable membrane is heated or cooled respectively”. While Applicant has not pointed to a specific element within the recitation not taught by Stimpson, Applicant appears to be arguing that Stimpson does not teach heating or cooling the membrane. This argument has been considered but is not found persuasive. It is noted that the claim requires passing a heated or cooled fluid through a membrane whereby the membrane is heated. The claim does not require heating and/or cooling the membrane to a constant or specific temperature or for a specific time period. Stimpson teaches passing a heated (i.e. 45° C) fluid through the membrane (Column 15, line 66-Column 16, line 1). This heated fluid application would inherently heat the membrane to which it is applied to at least some degree for at least some period of time. Hence, the method of Stimpson meets the limitations of the claim.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2- 7 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson (U.S. Patent No. 6,037,186, filed 16 July 1997) in view of Lipshutz et al (U.S. Patent No. 5,856,174, issued 5 January 1999).

Regarding Claim 2, Stimpson discloses the integrated support wherein the material of said base member is selected from a porous material, a fibrous material or an impregnating material (Column 10, lines 16-57 and Column 14, lines 8-10 and 45-48).

Regarding Claim 3, Stimpson discloses the support wherein said base member is arranged in such a way that the base member either prevents or enables expansion while bringing side portions into contact with each other or maintaining spacing or sandwiching (Column 5, line 47-Column 6, line 7 and Fig. 1A and 2C).

Regarding Claim 4, Stimpson discloses the support wherein markings are attached to said base member for identifying the chemical structure (Column 7, lines 49-60 and Column 13, lines 18-20 and 40-41).

Regarding Claim 5, Stimpson discloses the support further comprising a binding section (i.e. adhesive) for binding said base member and/or an auxiliary member in such a way that the auxiliary is either releasable or non-releasable (i.e. when the support is rod shaped the rods are arranged in a sheath which secures the rod arrangement, Column 13, lines 42-43 and when the support is a long and slender shape the base member is rolled the integrity of the rolled base member is maintained Column 6, lines 2-6 and where either base member is secured with an adhesive which provides a solid integrated support i.e. non-releasable Column 5, lines 56-61).

Regarding Claim 6, Stimpson discloses the support wherein said binding section is an adhesive portion for bonding side portion of said base member (Column 5, lines 48-65).

Regarding Claim 7, Stimpson teaches an integrated support comprising at least one base member, a variety substances for detection of predetermined chemical structure fixed side by side (and at intervals) along the length of the base member wherein said base member is

integrated whereby a fixed location of each substance identifies the chemical structure wherein the shape of the base member is selected from a rod shape and a long and slender shape, wherein the means for integration is arranging (a rod member) or rolling (a long and slender member) and wherein each substance is fixed at a location consisting of on the surface of the base member and channels in the base member (Column 3, line 46-Column 5, line 39; Column 12, line 42-Column 13, line 67; and Fig. 2A-E) wherein the integrated support comprises a linear member (cylindrical support) embedded inside the base member (Column 6, lines 59-63 and Fig. 2 #240) and Stimpson teaches that the support is exposed to fluids of differing temperatures (Example 5, Column 15, line 37-Column 16, line 13) but Stimpson is silent regarding the thermal properties (i.e. homoiothermal) of the embedded member. Lipshutz teaches a similar integrated support comprising a rod shaped and/or long and slender shaped base member (i.e. capillaries Column 11, lines 59-64) and a variety of substances fixed side by side along the length of said base member wherein said base member is arranged to give integration and wherein a thermal member is embedded inside said base member for controlling and maintaining uniform temperature within integrated support (Column 19, lines 1-4) wherein the thermal member is linear (Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the integrated support of Stimpson by embedding a thermal member for maintaining a uniform temperature as taught Lipshutz et al (Column 19, lines 1-4) and as instantly claimed. The thermal member of Lipshutz et al would permit the integrated support used to control and maintain appropriate temperatures while utilizing the integrated support of Stimpson. Therefore, one of ordinary skill would have been motivated to integrate the thermal member of Lipshutz et al into the integrated support of Stimpson for the expected benefits of controlling and maintaining desired temperatures in hybridization applications of Stimpson (Examples 5-6, Column 15, line 37-Column 16, line 30)

Regarding Claim 37, Stimpson discloses a method of using an integrated medium of Claim 1 comprising: a processing step for detecting a substance using an integrated support and a measuring step for conducting measurements of an optical state on an outside layer surface with the integrated support (Examples 5-6; Column 15, line 37-Column 16, line 30; and Claims 10-11).

Regarding Claim 38, Stimpson discloses the method wherein the measuring involves identification of an absolute location on the surface i.e. address-specific position is detected and measured (Examples 5-6; Column 15, line 37-Column 16, line 30; and Claim 10 (e)).

#### **Response to Arguments**

7. Applicant argues that Lipshutz teaches away from the instant invention because they teach a heater is provided in association with a chamber used to process samples rather than being provided within the samples. The argument has been considered but is not found persuasive because the claims are drawn to a homoiothermal member embedded inside a base member and/or an auxiliary member. Hence, Applicant's assertion that the instant claim requires a heater provided within the samples is not commensurate in scope with the claims. Furthermore, Lipshutz teach the heater "within or adjacent to the amplification chamber". The claim requires homoiothermal member embedded inside an auxiliary member.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the broad claim language wherein auxiliary member is undefined. Given the broadest reasonable interpretation of the claim, the amplification chamber of Lipshutz is encompassed by the claimed "auxiliary member".

Applicant argues that the references do not teach or suggest their combination. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Lipshutz et al teach the thermal member is useful for maintaining desired temperatures (Column 19, lines 1-4) and Stimpson used their membrane at specific temperatures (Example 5). Hence, one of ordinary skill would have been motivated to integrate the thermal member of Lipshutz et al into the integrated support of Stimpson for the expected benefits of controlling and maintaining desired temperatures in membrane applications of Stimpson (Examples 5-6, Column 15, line 37-Column 16, line 30).

**8. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### Conclusion

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

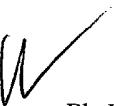
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
July 21, 2004